

**REMARKS/ARUGMENTS**

Upon entry of this amendment, claims 8-10 and 13 and 22 will be canceled without prejudice or disclaimer of the subject matter recited therein, claims 1, 2, 5, 14-16, 19 and 23 will be amended, and claims 25-36 will be added, whereby claims 1-7, 11, 12, 14-21 and 23-36 will be pending. Claims 1, 14, 15, 25, 26 and 33 are independent claims.

Reconsideration and allowance of the application are respectfully requested.

**Discussion of November 18, 2003 Interview**

Applicants express appreciation for the courtesies extended by Examiners Caputa and Holleran during a November 18, 2003 personal interview with Applicants' representative Arnold Turk. During this interview, the Examiners confirmed allowable subject matter with respect to claims 2-7 and 16-23 which were not rejected in the Office Action, and were only indicated as objected to on the Cover Sheet of the Office Action. Still further, the Examiners indicated that claims directed to glycerophospholipid or fatty acids should also be allowable.

The terminology "indocyanine green derivative which is capable of being excited to cause fluorescence" was also discussed with the Examiners, and the Examiners indicated that arguments should once again be presented that such derivatives would be readily understandable by one having ordinary skill in the art.

Regarding the prior art rejections, the Examiners discussed statements made in the rejections of record in the Office Action, and indicated that they might favorably consider specifically recited species having fluorescence intensity enhancing effect, i.e., octyl glucoside,

heptyl glucoside, octyl thioglucoside, or heptyl thioglucoside with arguments being submitted in response to the rejections of record based upon the disclosure of Klemt.

**Consideration Of Disclosure Statement**

Applicants express appreciation for the inclusion with the Office Action of copies of the initialed Forms PTO-1449, whereby the Examiner's consideration of the Information Disclosure Statement, filed November 5, 2001, and the Supplemental Information Disclosure Statement, filed March 4, 2002, is of record.

**Claim Of Priority**

Applicants express appreciation for the acknowledgment in the Office Action of the claim of foreign priority as well as receipt of the certified copies of the priority documents, which were filed in parent Application No. 09/147,839.

**Formal Drawings**

Applicants express appreciation for the approval of the drawings filed October 7, 2002, and are submitting formal drawings including the approved changes.

**Objection To Claim**

Applicants note that the objection to claim 10 under 37 C.F.R. 1.75(C) as failing to further limit the scope of claim 1 has been rendered moot by the cancellation of claim 10. Accordingly, this ground of objection should be withdrawn.

**Allowability Of Objected To Claims**

Claims 2-7 and 16-23 are not included in the prior art rejections, but are indicated on the Cover Sheet of the Office Action to be objected claims. These claims are therefore allowable over the prior art of record, but are objected to for depending upon rejected claims.

As discussed with the Examiners during the above-noted interview, claim 1 has been amended herein to recite “at least one substance which enhances fluorescence intensity of the fluorescent functional group, said at least one substance being selected from glycerophospholipid or fatty acid”. Accordingly, as indicated by the Examiners during the above-noted interview, claims 1-7, 11, 12, 14-21 and 24 should presently be in condition for allowance.

Still further, objected to claim 22 has been rewritten to substantially include its recitation in new independent claim 25. Therefore, independent claim 25 and claim 23 which depends therefrom should also be in condition for allowance.

**Response To Rejections Based Upon Prior Art**

The following rejections are set forth in the Office Action:

- (a) Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Mishra, Acta Chimica Hungarica 116(1):5-12, 1984 or Kapoor, J. of Luminescence, 22:429-439, 1981.
- (b) Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Klemt, U.S. Patent No. 5,677,192 - It is noted that it is based upon a PCT application that published November 10, 1994 as WO 94/25853 which qualifies as 102(b) prior art.
- (c) Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karandikar, U.S. Patent No. 6,207,464, in view of either of Mishra, Acta Chimica Hungarica 116(1):5-12, 1984 or Kapoor, J. of Luminescence, 22:429-439, 1981. - It is noted that Karandikar is a divisional of U.S. Patent No. 5,852,191.
- (d) Claims 1, 10, 12, 14, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karandikar, U.S. Patent No. 6,207,464, in view of either of Mishra, Acta Chimica Hungarica 116(1):5-12, 1984 or Kapoor, J. of Luminescence, 22:429-439, 1981, and further in view of Sykes et al., U.S. Patent No. 6,313,274,. - It is noted that Sykes is based upon a PCT application that published January 20, 1994 as WO 94/01773 which qualifies as 102(b) prior art.
- (e) Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karandikar, U.S. Patent No. 6,207,464, in view of Klemt, U.S. Patent No. 5,677,192.

- (f) Claims 1, 10-12, 14, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito, Bioorganic and Medicinal Chemistry Letters 5(22): 2689-2694, 1995, in view of either of Mishra, Acta Chimica Hungarica 116(1):5-12, 1984 or Kapoor, J. of Luminescence, 22:429-439, 1981, and further in view of Sykes et al., U.S. Patent No. 6,313,274.

With regard to the above-noted rejections, Applicants note that claim 13 has been canceled, whereby the rejections of claim 13 have been rendered moot.

Regarding the obviousness rejections, these rejections rely on either Karandikar or Ito as primary references.

With respect to Karandikar, Applicants note that Karandikar discloses a number of fluorescent materials in the background of his invention. However, Karandikar's invention is directed to boron-rigidized monomethine cyanine complexes. Following the disclosure of Karandikar, one having ordinary skill in the art would not have been led to indocyanine green or its derivatives. During the above-noted interview, arguments were presented that one having that one having ordinary skill in the art would readily understand the terminology "indocyanine green or its derivatives", and that "indocyanine green or its derivatives" would not include boron-rigidized monomethine cyanine complexes as disclosed in Karandikar. For example, indocyanine green or its derivatives would include an indocyanine green backbone. As discussed with the Examiners during the above-noted interview, indocyanine green and its derivatives are thoroughly discussed in Applicants' specification, such as at page 2, beginning in the second full paragraph, and at page 10, beginning in the second full paragraph.

Regarding the disclosures of each of Mishra and Kapoor, Applicants note that Mishra and Kapoor disclose surfactants, but do not disclose surfactants in combination with indocyanine green derivatives nor are they directed to the surfactants recited in Applicants' presently pending claims.

Klemt is directed to electrochemiluminescent phenomena, and does not appear to provide motivation for modifying Karandikar and/or modifying a composition containing indocyanine green derivatives. For example, the subject matter of Klemt is directed, as disclosed at column 1, lines 48-53, to a method of measuring electrochemical phenomena in a solution or a solid phase contiguous with the solution, wherein the solution is a detergent selected from the group consisting of fat alcohol ethoxylate, Plantaren, and octylglucoside or a mixture thereof. Moreover, Klemt discloses, at column 2, lines 12-23, certain disadvantages with respect to the use of Triton X-100, and indicates that experience has surprisingly shown that certain other detergents improve the signal/noise ratio thus achieving higher sensitivity of the detection, lowering the lower detection threshold, and achieving a better precision as compared to Triton X-100. Still further, Klemt discloses, at column 2, line 50 et seq., that the sensitivity can further be increased by applying a square-wave voltage to the measuring unit. Accordingly, the disclosure of Klemt is directed to chemiluminescence assays and providing improvements thereto, and one having ordinary skill in the art would not be motivated to combine its disclosure with the disclosure of Karandikar to arrive at Applicants' disclosed and claimed invention.

Sykes is merely utilized with respect labeling antibodies with a fluorophore that bind to tumor antigens, and does not make up for the deficiencies of the rejections.

Regarding the rejection utilizing Ito, it is noted that Ito discloses indocyanine green derivatives. However, Ito does not teach or suggest Applicants' disclosed and claimed invention. Moreover, the subject matter recited in Applicants' claims 25-36 does not appear to be included in the subject matter over which Ito is utilized as a primary reference. Therefore, each of the pending claims should be allowable over Ito alone or in combination with the prior art of record.

In view of the above, the rejections of record should be withdrawn.

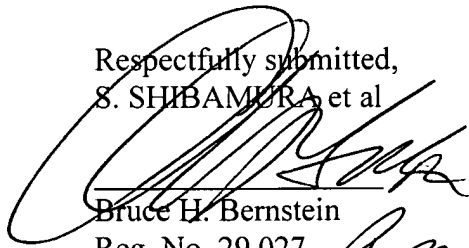
### CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicant therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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